

Exhibit I

D3
4-5
7-B

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): P. Bonutti

Application No.: 10/003,996

Filed: November 15, 2001

For: APPARATUS AND METHOD FOR TISSUE
REMOVAL

Attorney Docket No: 780-A02-014-8

Group Art Unit: 3731

Examiner: J. Baxter

D3
#7/8RESPONSE TO OFFICE ACTIONMail Stop AMENDMENT - FEB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Introductory Comments

Dear Sir:

In response to the Office Action mailed December 30, 2002, please enter the following amendments and remarks into the file for the above-identified application. In accordance with USPTO practice, each section of this Amendment begins on a separate sheet. Claims 36-47, 49, and 51-76 remain in this application and are submitted for the Examiner's review and consideration. Applicant has canceled claims 1, 48, and 50 and amended claims 36, 38, 40-47, 49, 51-61, 69, 71-74, and 76, with claims 40, 41, 53, 56, 60, and 71 rewritten in independent form. Applicant believes these amendments serve to clarify the present invention and are independent of patentability.

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to:

Group Art Unit 3731, at Fax # (703) 305-3590,

ASSISTANT COMMISSIONER FOR PATENTS, WASHINGTON, D. C. 20231

ATTENTION: Patent Examiner Jessica BAXTER

On March 31, 2003

Paul Blanco

Name of Person Transmitting Facsimile

Signature of Person Transmitting Facsimile

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

Amendments to the Claims

1. (Canceled)

2-35. (Previously canceled)

B1 36. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed from the patient's body, thereafter packing the removed tissue, and implanting the packed tissue at a second location in the patient's body ~~after separating one or more components from at least a portion of the tissue~~.

37. (Previously added) A surgical procedure as set forth in claim 36 wherein said step of separating one or more components from the tissue removed from the patient's body includes centrifuging at least a portion of the tissue removed from the patient's body.

38. (Currently amended) A surgical procedure as set forth in claim 36 further including the step of adding a substance to the body tissue after separating one or more components from the body tissue and prior to implanting the packed body tissue at a second location in the patient's body.

39. (Previously added) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes cutting body tissue at the first location and moving the body tissue away from the first location under the influence of suction.

B2 40. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed from the

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

patient's body, and implanting the tissue at a second location in the patient's body after separating one or more components from at least a portion of the tissue, wherein said step of removing tissue from a first location in a patient's body includes cutting body tissue at the first location and moving the body tissue away from the first location under the influence of suction and as set forth in claim 39 wherein said step of cutting body tissue includes rotating a cutting tool under the influence of force transmitted through an elongated member which is at least partially enclosed by a tubular member, said step of moving the body tissue away from the first location under the influence of suction includes moving body tissue cut by the rotating cutting tool along the tubular member under the influence of suction.

32
41. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of removing tissue from a first location in the patient's body, separating one or more components from at least a portion of the tissue removed from the patient's body, and implanting the tissue at a second location in the patient's body after separating one or more components from at least a portion of the tissue, as set forth in claim 36 wherein said step of implanting the tissue at the second location includes inserting a cannula into the patient's body, moving a surgical instrument through the cannula, removing tissue from the second location, said step of removing tissue from the second location includes using the surgical instrument inserted through the cannula, and, thereafter, performing said step of inserting tissue removed from the first location in the patient's body at the second location in the patient's body.

42. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes removing blood from the first location in the patient's body, said step of separating one or more components from the tissue removed from the patient's body includes separating one or more components from blood removed from the patient's body, said step of implanting the packed tissue at a second location in the patient's body includes implanting one or more components of the blood removed from the patient's body.

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

43. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from the first location in the patient's body includes removing blood and other tissue from the first location in the patient's body, said step of separating one or more components from the tissue removed from the patient's body includes separating at least a first component from blood removed from the patient's body, said step of implanting the packed tissue at a second location in the patient's body includes implanting the blood removed from the patient's body after removing at least the first component from the blood and implanting at least a portion of the other tissue removed from the patient's body.

B 2
44. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes removing at least blood from the first location, said step of separating one or more components from the tissue removed from the patient's body includes removing at least a first component from the blood removed from the patient's body, said step of implanting the packed tissue at the second location includes implanting at least the blood from which at least the first component has been removed.

45. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes removing blood and other tissue from the first location, said step of separating one or more components from the tissue removed from the patient's body includes centrifuging the blood and other tissue removed from the first location, said step of implanting the packed tissue at a second location is performed after centrifuging the blood and other tissue removed from the first location.

46. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes removing blood and other tissue from the first location, said step of separating one or more components from the tissue removed from the patient's body includes filtering the blood and other tissue removed from the first location, said step of implanting the packed tissue at a second location is performed after filtering the blood and other tissue removed from the first location.

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

B2 47. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes removing blood and other tissue from the first location, said step of separating one or more components from the tissue removed from the patient's body includes moving the blood and other tissue removed from the first location into a trap, said step of implanting the packed tissue at a second location is performed after moving the blood and other tissue removed from the first location into the trap.

48. (Canceled)

B3 49. (Currently amended) A surgical procedure as set forth in claim 36 wherein said step of removing tissue from a first location in a patient's body includes inserting a first tubular member into a patient's body and moving the body tissue from the first location in the patient's body through the first tubular member to a location outside of the patient's body, said step of implanting the packed tissue at a second location in the patient's body includes inserting a second tubular member into the patient's body and moving the tissue through the second tubular member.

50. (Canceled)

B4 51. (Currently amended) A surgical procedure as set forth in claim 53 50 further including the step of separating one or more components from at least a portion of the body tissue moved through the first tubular member prior to performance of said step of moving body tissue through the second tubular member to the second location in the patient's body.

52. (Currently amended) A surgical procedure as set forth in claim 53 50 further including the step of centrifuging at least a portion of the body tissue moved through the first tubular member to separated one or more components from the body tissue prior to performing said step of moving the body tissue through the second tubular member.

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

53. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, inserting a second tubular member into the patient's body, and moving at least a portion of the body tissue through the second tubular member to a second location in the patient's body, wherein as set forth in claim 50 further including the step of adding a substance is added to the body tissue after moving the body tissue from the first location through the first tubular member to a location outside of the patient's body and prior to moving the body tissue through the second tubular member, and wherein the added substance is a bone growth promoter.

B4 54. (Currently amended) A surgical procedure as set forth in claim 53 50 wherein said step of moving the body tissue from the first location through the first tubular member includes moving the body tissue through the first tubular member under the influence of suction.

55. (Currently amended) A surgical procedure as set forth in claim 53 50 further including the step of cutting body tissue at the first location with a cutting tool which is driven under the influence of force transmitted through the first tubular member.

56. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, inserting a second tubular member into the patient's body, as set forth in claim 50 further including the step of moving a surgical instrument through the second tubular member, and removing tissue from a second location with the surgical instrument, prior to moving body tissue through the second tubular member to the second location and moving at least a portion of the body tissue through the second tubular member to the second location in the patient's body.

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

34 57. (Currently amended) A surgical procedure as set forth in claim 53 50 wherein said step of moving body tissue from a first location in the patient's body through the first tubular member includes moving blood from the first location in the patient's body through the first tubular member, said surgical procedure further includes separating one or more components from the blood, said step of moving body tissue through the second tubular member to the second location in the patient's body includes moving the blood from which one or more components have been removed through the second tubular member to the second location in the patient's body.

58. (Currently amended) A surgical procedure as set forth in claim 53 50 wherein said step of moving tissue from the first location in the patient's body through a first tubular member includes moving blood and pieces of other tissue through the first tubular member, said surgical procedure further includes filtering the blood and other tissue move through the first tubular member, said step of moving body tissue through the second tubular member is performed after filtering the blood and other tissue.

59. (Currently amended) A surgical procedure as set forth in claim 53 50 wherein said step of moving tissue from the first location in the patient's body through a first tubular member includes moving blood and pieces of other tissue through the first tubular member, said surgical procedure further includes moving the blood and other tissue into a trap, said step of moving body tissue through the second tubular member is performed after moving the blood and other tissue into a trap.

60. (Currently amended) A surgical procedurc to be conducted on a patient, said surgical procedure comprising the steps of inserting a first tubular member into the patient's body, moving body tissue from a first location in the patient's body through the first tubular member to a location outside of the patient's body, as set forth in claim 50 further including the step of packing tissue moved through the first tubular member to form a body of packed tissue, inserting a second tubular member into the patient's body, and, said step of moving the body tissue

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

~~through the second tubular member includes moving the body of packed tissue through the second tubular member to a second location in the patient's body.~~

61. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the step of removing blood and other body tissue from a first location in the patient's body, shaping the blood and other body tissue to form a body of tissue having a desired shape, and implanting the body of tissue at a second location in the patient's body, wherein the blood and other body tissue are free of tanning substances. *New matter*

62. (Previously added) A surgical procedure as set forth in claim 61 further including the step of separating one or more components from at least a portion of the blood removed from the first location in the patient's body prior to shaping the blood and other body tissue to form a body of tissue having a desired shape.

63. (Previously added) A surgical procedure as set forth in claim 61 further including the step of separating one or more components from at least a portion of the other body tissue removed from the first location in the patient's body prior to shaping the blood and other body tissue to form a body having a desired shape.

64. (Previously added) A surgical procedure as set forth in claim 61 further including the step of separating one or more components from at least a portion of the blood and other body tissue removed from the first location in the patient's body prior to shaping the blood and other body tissue to form a body of tissue having a desired shape.

65. (Previously added) A surgical procedure as set forth in claim 61 wherein said step of implanting the body tissue at the second location includes changing the shape of body of tissue.

66. (Previously added) A surgical procedure as set forth in claim 61 wherein said step of removing blood and other body tissue from a first location in the patient's body includes moving

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

the blood and other body tissue along a first tubular member, said step of implanting the body of tissue at a second location in a patient's body includes moving the body of tissue along a second tubular member.

67. (Previously added) A surgical procedure as set forth in claim 61 further including the step of centrifuging the blood prior to performing said step of shaping the blood and other body tissue.

68. (Previously added) A surgical procedure as set forth in claim 61 further including the step of centrifuging the other body tissue prior to performing said step of shaping the blood and other body tissue.

69. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of cutting body tissue at a first location in a patient's body, moving blood and other body tissue along a first tubular member in a direction away from the first location in the patient's body to a location outside of the patient's body, separating one or more components from at least one of the blood and other body tissue at a location outside of the patient's body, thereafter, packing the blood and other body tissue to form a packed tissue mass, moving the packed tissue mass blood and other body tissue along a second tubular member in a direction toward a second location in the patient's body, and implanting the packed tissue mass blood and other body tissue at the second location in the patient's body.

70. (Previously added) A surgical procedure as set forth in claim 69 wherein said step of separating one or more components from at least one of the blood and other body tissue includes centrifuging the blood.

71. (Currently amended) A surgical procedure to be conducted on a patient, said surgical procedure comprising the steps of cutting body tissue at a first location in a patient's body, moving blood and other body tissue along a first tubular member in a direction away from the

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

first location in the patient's body to a location outside of the patient's body, separating one or more components from at least one of the blood and other body tissue at a location outside of the patient's body, thereafter, moving the blood and other body tissue along a second tubular member in a direction toward a second location in the patient's body, and implanting the blood and other body tissue at the second location in the patient's body as set forth in claim 69 wherein said step of separating one or more components from at least one of the blood and other body tissue includes centrifuging the other body tissue.

72. (Currently amended) A surgical procedure as set forth in claim 71 69 wherein said step of separating one or more components from at least one of the blood and other body tissue includes centrifuging the blood ~~and the other body tissue~~.

73. (Currently amended) A surgical procedure as set forth in claim 69 further including the step of adding a substance to the packed tissue mass blood ~~and other body tissue~~ prior to moving the packed tissue mass blood ~~and other body tissue~~ along the second tubular member.

74. (Currently amended) A surgical procedure as set forth in claim 69 wherein said step of moving the packed tissue mass blood ~~and other body tissue~~ along a first tubular member includes moving the packed tissue mass blood ~~and other body tissue~~ under the influence of suction.

75. (Previously added) A surgical procedure as set forth in claim 69 wherein said step of cutting body tissue at the first location in a patient's body includes rotating a cutting tool under the influence of force transmitting through the first tubular member.

76. (Currently amended) A surgical procedure as set forth in claim 69 further including the steps of moving a surgical instrument through the second tubular member and removing the tissue from the second location before moving the packed tissue mass blood ~~and other body tissue~~ along the second tubular member.

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

Remarks

Double Patenting Rejections

Claims 36-40 and 48-49 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5, 7, 19, 20, and 21 of U.S. Patent No. 5,403,317. Furthermore, claims 36, 37, 39, 40 and 48 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,694,951. In response and in order to expedite the prosecution of this application, Applicant submits herewith Terminal Disclaimers to obviate these double patenting rejections. It should be understood that these Terminal Disclaimers are being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimers are necessary.

In addition, claim 1 was rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,269,785. In response, Applicant has canceled claim 1.

35 U.S.C. §102 Rejection

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,857,045 to Rydell. As previously noted, Applicant has canceled claim 1.

Claims 36-39, 42-47, 49-55, 57-59; 69, 70, 73 and 74 were rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 5,226,877 to Epstein ("Epstein"). For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Epstein.

Epstein teaches a method for preparing fibrinogen adhesive in which the process begins with the withdrawal of whole blood from an autologous, or other, or multiple donors in the presence of an anticoagulant, and separation of plasma from the red blood cell fraction. (col. 6, lines 1-4). After the plasma is separated from the red blood cells, it is treated directly, at ambient temperature, without prior treatment to remove thrombin, with a physiologically acceptable non-toxic precipitant. (col. 6, lines 16-20). The concentrated solution or, in some instance, undiluted

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

precipitant is added to the plasma in an amount effective to precipitate the fibrinogen adhesive composition of the invention. (col. 6, lines 37-40). The precipitate containing the fibrinogen adhesive is then recovered, typically by centrifugation. (col. 6, lines 54-55). Commercial preparations of thrombin and calcium ion may be added with the fibrinogen adhesive. (col. 10, lines 48-50). In a particularly advantageous way to apply the two components of the sealant to the tissue to be cemented, a dual-barreled applicator with one barrel for supply of the fibrinogen adhesive and the other for the thrombin/calcium ion mixture is employed. (col. 10, lines 53-57).

In contrast, Applicant discloses a surgical procedure for tissue harvesting in which hard or soft tissue of the body is removed for possible re-implantation. Removed tissue may be centrifuged if necessary or desired, keeping the components such as bone, cells, and blood and discarding fluid. The surgeon can place other substances into the graft material to be implanted, such as other tissue graft material, collagen, antibiotics, or ceramic hydroxyapatite or tricalcium phosphate to aid in bone ingrowth. Before implantation, harvested tissue fragments are preferably packed or compressed into a plug of tissue graft material. Alternatively, the tissue fragments may be left in a more loose state, or only certain selected cells, components, or tissue fragments are used. Any suitable means of packing or compressing fragments may be used.

Therefore, to further highlight these distinctions of the present invention, Applicant has amended independent claims 36 and 69 to be in a form analogous to claim 48, against which no prior art was cited. Claim 48 has been canceled. Independent claim 50 has also been canceled and claim 53 has been rewritten in independent form to include all the elements of canceled claim 50. Claim 53 also now further specifies that a bone growth promoter is added to the body tissue prior to implantation. Epstein does not teach or suggest at least this feature since Epstein is directed to a method of making an adhesive from blood components.

Based on the foregoing, Applicant respectfully submits that independent claims 36, 53, and 69 are now in condition for allowance. Based at least on their dependency, Applicant also respectfully submits that dependant claims 37-39, 42-47, 49, 51, 52, 54-55, 57-59, 70, and 73-74 are allowable as well.

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

35 U.S.C. §103 Rejection

Claims 61-69 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,678,470 to Nashef *et al.* ("Nashef") in view of Epstein. Specifically, the Examiner states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to use blood derived adhesive of Epstein to adhere the bone grafting material of Nashef into the implantation site. For the reasons set forth below, Applicant respectfully submits that the rejected claims as amended are not taught or suggested by Nashef and Epstein, either alone or in combination.

Nashef discloses a biologically derived, biocompatible, non-antigenic, and incorporatable material for use as a generic bone substitute, as well as the process for making this material. The bone substitute material is derived from glutaraldehyde-tanned bone. (col. 1, lines 56-60).

In contrast, the present invention teaches a surgical procedure for harvesting tissue. One or more selected components can be separated from the harvested tissue fragments. (col. 4, lines 21-22). The selected components may include bone, cells, and blood. (col. 9, lines 1-2). The harvested tissue and/or the selected components are then implanted into the body of a patient. (col. 4, lines 23-24). As previously noted, a number of substances can be added to the implanted tissue. However, none of the substances identified in the specification are tanning agents or have the effect of a tanning agent.

Applicant has amended claim 61 to include tissue free from tanning substances. Applicant respectfully submits that independent claim 61 is now in condition for allowance. Based at least on their dependency, Applicant submits that claims 62-68 should be allowable as well. In regard to independent claim 69, Applicant respectfully submits that the §103 rejection should be withdrawn. Applicant contends that the amendment made to this claim with respect to the §102 rejection is applicable here as well.

Subject Matter Indicated as Being Allowable

Applicant acknowledges with appreciation that claims 41, 56, 71, 72, 75, and 76 were indicated as being allowable if rewritten in independent form. In response, Applicant has rewritten claims 41, 56, and 71 in independent form. Claim 72 has been rewritten to depend from claim 71

Applicant: P. Bonutti
Application No.: 10/003,996
Examiner: J. Baxter

and claims 75 and 76 remain dependent from claim 69, which is believed to be in condition for allowance.

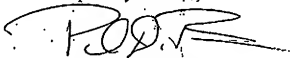
Applicant notes that no prior art was cited against claims 40 and 60. In order to expedite prosecution of this case, Applicant has amended claims 40 and 60 to be in independent form. In amending these claims to be in independent form, Applicant has included all the elements of the base claim. Accordingly, Applicant respectfully submits that claims 40 and 60 are now in condition for allowance.

Conclusion

In light of the foregoing, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of \$278.00 is believed to be due for two terminal disclaimers plus four additional independent claims (at small entity rate) is believed to be due with this submission and a Fee Transmittal Sheet including this fee is submitted concurrently herewith. Please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-014-8).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
Paul D. Bianco
FLEIT KAIN GIBBONS GUTMAN & BONGINI
601 Brickell Key Drive, Suite 404
Miami, Florida 33131
Tel: 305-931-9620; Fax: 305-931-9627
e-mail: pbianco@focusonip.com